DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not reiterated in this Action is withdrawn.

This application has been assigned to a different examiner.

Election/Restrictions

Applicant's election without traverse of SEQ ID NO: 35 in the reply filed on April 25, 2011 is acknowledged.

Claims 34-38 and 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/24/2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlingensiepen et al. (EP 1,133,988).

Schlingensiepen et al. disclose compositions of an inhibitor or suppressor of expression of a gene and a molecule binding to expression product of the gene. Particularly preferred expression inhibitors include the antisense oligonucleotides disclosed in paragraph 14; one of which, SEQ ID NO: 5, is identical to instantly claimed SEQ ID NO: 35. Schlingensiepen et al. further disclose (see paragraph 25) administration of these compositions in order to treat tumors. While Schlingensiepen et al. do not explicitly disclose that performing this method will inhibit the formation of metastases, because Schlingensiepen et al. disclose a method sharing the identical step of the claimed method, performing this method is considered in the absence of factual evidence to the contrary to provide the claimed outcome.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 27-30 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlingensiepen et al. (WO 99/63975, cited on IDS).

Schlingensiepen et al. teach and claim compositions (medicaments) and methods of treating disease. At page 6 Schlingensiepen et al. teach that in one embodiment the composition comprises an oligonucleotide. Preferably the oligonucleotides of Fig. 1 are useful in the medicament of the present invention. These oligonucleotides include several TGF-β2 sequences that are recited in the instant claims. At page 8 Schlingensiepen et al. teach that the medicaments of the invention can be used to treat hyperproliferative diseases or neoplasms by administering the medicament to patients in need thereof. Specific cancers that can be treated include colorectal carcinoma, pancreatic carcinoma and prostatic carcinoma.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the oligonucleotides shown in figure 1 of Schlingensiepen et al. to treat cancer, including colorectal carcinoma, pancreatic carcinoma and prostatic carcinoma. Several of the claimed sequences (particularly SEQ ID NOs: 28, 29, 34, 35, 40 and 42) are found in this figure. One would have reason to use these sequences and would expect success in doing so because Schlingensiepen et al. teach that these sequences are suitable for use as medicaments and specifically contemplate their use in treating the types of cancers claimed (see claims 1, 3, 5, 12 and 13). While Schlingensiepen et al. do not explicitly teach that performing this method will provide the outcome of inhibiting formation of metastases, because Schlingensiepen et al. teach a

method sharing the identical step of the claimed method that uses the same sequences, performing this method is considered in the absence of factual evidence to the contrary to provide the claimed outcome.

Response to Arguments

In the response and declaration filed January 18, 2011 applicants note a difference between the teachings of the cited references and what is presently claimed, specifically that metastases and primary tumors often substantially differ in their gene expression and thus in their reaction to inhibitors. Applicants argue that because the methods described in the cited references concern the application of TGF-beta 2 antisense oligonucleotides to treat primary tumors, while the present claims are directed to inhibiting the formation of cancer metastases, the combined teachings of the previously cited references is not sufficient to render the claimed methods obvious. Based on the combination of references, the person skilled in the art could not have expected that a treatment with TGF-beta2 antisense oligonucleotides might be successful in inhibiting the formation of metastases.

This argument is not persuasive with regard to the newly applied rejections because the newly cited references either disclose or specifically suggest the identical step of the claimed method: administration of a TGF-β2 antisense to a subject with cancer. While the cited references may not explicitly contemplate performing this claimed method for the purpose of treating/preventing metastasis, because the step is identical it is assumed in the absence of factual evidence to the contrary that performing this step will provide the claimed outcome.

Applicants further argue the office has not satisfied its burden with regard to establishing inherency; asserting that the characteristic of metastases formation inhibition by the specific TGF-β2 antisense oligonucleotides currently claimed does not necessarily flow from the teachings of the cited references or the combination thereof.

This is not persuasive because, as noted above the claimed characteristic of inhibiting metastasis flows from performing the claimed step with the claimed sequences. Because the methods taught by the cited art uses the same sequences in the same way by administering to cancer patients it is expected that performing the methods taught by the prior art will provide the claimed effect.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita, can be reached on 571-272-2876. The central FAX Number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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